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Section 2 - 510(k) Summary

APR 22 2009

Pursuant to Section 12, Part (a)(i)3A of the Safe Medical Devices Act of 1990, Surgical Technology Laboratories, Inc. is providing a summary of the substantial equivalence decision making process proposed by Surgical Technology Laboratories and the safety and effectiveness information available for the PureForm ePTFE Facial Implants.

Applicant Name

Surgical Technology Laboratories, Inc ("STL")
610 Clemson Road
Columbia, SC 29229
Tel: (803) 462-1714
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Contact Person Mathew Fairfax, President

Date Prepared April 8, 2009

Device Trade Name PureForm ePTFE Facial Implants (Nasal, Chin, Malar)

Device Common Name Facial Implant (Prosthesis)

Classification Name Implant, Nasal (LZK)

Predicate Devices

Gore-Tex SAM Facial Implant, manufactured by W. L. Gore and Associates, Flagstaff, AZ (K933367)

Surgiform Augmentation Material (SFAM), manufactured by Surgical Technology Laboratories, Inc., Columbia, SC (K021889)

Surgiform Silicone Facial Implants (Chin, Malar, Nasal), Manufactured by Surgical Technology Laboratories, Inc., Columbia, SC (K983754, K983755, K983756)

Implantech Composite Facial Implants (Malar, Chin, and Nasal), Manufactured by Implantech Associates, Inc., Ventura, CA (K002886)

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Device Description	The PureForm ePTFE Facial Implants are three-dimensional facial prosthesis (Nasal, Chin, and Malar) that are made from expanded Polytetraflouroethylene (ePTFE). The device is offered sterile in multiple sizes.
Intended Use	The PureForm ePTFE Facial Implants are indicated for use in plastic and reconstructive surgery.
Device Technological Characteristics and Comparison to Predicate Devices	The indications and intended use of the PureForm ePTFE Facial Implants are identical to those of the predicate facial implants. The material of fabrication of the PureForm Implants is the same as that of the Gore-Tex SAM, Surgiform Facial Augmentation Material (SFAM) and the lining of the Implantech Composite Facial Implants. The Surgiform PureForm ePTFE Facial Implants do not use or introduce any new technological characteristics.
Conclusions	Based on a comparison of indications and intended use, material of fabrication, similarity of design, and demonstrated biocompatibility the Surgiform PureForm ePTFE Facial Implants are substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Technology Laboratories, Inc
% Mr. Mathew Fairfax
President
610 Clemson Road
Columbia, South Carolina 29229

APR 22 2009

Re: K091011
Trade/Device Name: Surgiform's PureForm ePTFE Implants
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin prothesis
Regulatory Class: II
Product Code: LZK, FWP
Dated: April 8, 2009
Received: April 9, 2009

Dear Mr. Fairfax:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1 - Indications for Use

510(k) Number: K091011

Device Name: Surgiform's PureForm ePTFE Implants

Indications for Use:

PureForm ePTFE Facial Implants are indicated for use in facial plastic and reconstructive surgery.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for NDM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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